

Remarks

For the sake of convenience in examination, attached at the end of the present Remarks section is a redline version of the claims as they are amended by the present amendment, as compared to the previously filed amendment.

I. PENDING CLAIMS

Claims 1-4 and 8-27 are pending in this application. Claims 1-3 have been allowed. Claims 4 and 8-21 stand rejected, claims 22-27 have been recently added.

Of these, claims 12-14, 17 and 18 have been objected to as dependent on a rejected base claim, but indicated to be otherwise allowable. Claims 12, 17 and 18 have been rewritten in independent form, and are therefore deemed to be in condition for allowance. Claims 13-14 further limit claim 12 and are also deemed to be in condition for allowance.

II. SUPPORT FOR CLAIM AMENDMENTS

Applicant has amended claims 4, 9, 12, and 17-18.

As mentioned above, claims 12 and 17-18 were rewritten in independent form with some minor formatting changes and word changes to make the claims easier to read. No new matter has been added to these claims.

Support for the changes to claim 4 and 9 and for new claims 22-24 can be found in Figs. 1-3, taken collectively.

Support for new claim 25 can be at column 2, lines 33-38, column 6, lines 42-66, and Figs. 1-3, taken collectively.

III. ANTICIPATION REJECTION OVER MONSON

At page 2 of the Final Office action, the Examiner has rejected claims 4, 10, 11, 15, 16 and 19 under 35 U.S.C. § 102(b) as anticipated by Monson (U.S. Patent No. 4,863,477).

Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

In order for an anticipation rejection to be proper, the alleged anticipatory reference must,

within its four corners, teach an embodiment containing every element recited in the Applicants' claims. Monson fails in this respect; in fact, Monson uses an approach to inserting intervertebral discs that is diametrically opposed to that recited in Applicants' claims.

Claim 4 requires "forming concave, non cylindrical surfaces in the endplates of confronting vertebral bodies." Monson does not teach any way of forming surfaces in the endplates of any vertebral bodies. Instead, Monson discloses excising and removing damaged natural disc, including the annulus and inserting an intervertebral disc prosthesis made of synthetic material that is molded to the approximate size and shape of the natural disc that is to be replaced. See column 5, lines 30-32.

Thus, rather than prepare a prosthesis that has a shape corresponding to that of the natural disc, and that therefore mates with the natural shape of the endplates, Applicants' method takes the opposite approach of modifying the intervertebral space to correspond in shape to that of the prosthesis.

Because Monson teaches away from forming concave, non cylindrical surfaces in the endplates of confronting vertebral bodies, it fails to teach every element of claim 4, and therefore cannot be an anticipatory reference. The Examiner's rejection should therefore be withdrawn.

IV. OBVIOUSNESS REJECTION OVER SHEPPARD, MICHELSON

At page 3 of the Office action, the Examiner has rejected claim 8 under 35 U.S.C. § 103(a) as obvious over Sheppard (U.S. Patent No. 4,863,476) in view of Michelson (U.S. Patent No. 5,015,247). Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

The Examiner has apparently taken the position that Sheppard discloses an implant that has convex shells capable of motion relative to each other, apparently basing this assertion on the motion of the Sheppard body portions apart as the device is expanded to fit into the intervertebral space. The Examiner also apparently takes the position that the disclosure of Sheppard of inserting the device through a small incision would motivate one of ordinary skill in the art to combine the implant of Sheppard with the implantation method disclosed in Michelson, which also allegedly uses a small incision.

However, Applicants submit that introduction of a prosthesis through a small incision is

not sufficient basis for asserting that motivation exists for combining reference teachings, particularly reference teachings as disparate as those of Sheppard and Michelson.

First, in any surgical procedure, the surgeon's goal is to carry out the surgery with as small an incision as is possible. The use of a "small incision" as a common thread for motivation to combine reference teachings would support combination of virtually any disclosures of any surgical procedures – an untenable result.

Second, Sheppard completely fails to disclose or suggest any modification of the vertebral endplates to accommodate the prosthesis. To the contrary, in column 6, lines 19-29 (the same passage upon which the Examiner apparently relies for the teaching of a "small incision"), Sheppard teaches providing the cylindrical bodies with flattened surfaces to better fit against the vertebral bodies and prevent slippage. Michelson cuts away plugs of bone and cartilage (hardly a "small" incision by any surgeon's definition) in order to introduce his fusion cage into the intervertebral space. Thus, the Examiner is, in effect, asserting that a worker of ordinary skill would have been motivated to implant a prosthetic, disclosed in Sheppard as having a shape modified to fit the natural intervertebral space, using a procedure disclosed in Michelson for introducing a prosthetic into an intervertebral space that has been modified to match the shape of the prosthetic. Applicants respectfully submit that this is incorrect: that the approaches of (1) developing an implant shaped to fit into the natural intervertebral space and (2) modifying the intervertebral space to conform to the shape of the implant are diametrically opposed, and not combinable.

Third, and as discussed in Applicant's previous response, Michelson teaches away from using an implant that can rock. See Michelson at column 4, lines 45-55 and at column 10, lines 53-56. See also, Applicants' Amendment dated April 5, 2002 at pages 9-11. Given that the Sheppard implant can undergo a rocking motion, there would not have been any motivation for one of ordinary skill in the art to use it in the implantation process of Michelson.

For each of these reasons, the Examiner's conclusion that a worker of ordinary skill in this art would have been motivated to use the implant of Sheppard in the implantation process of Michelson is incorrect. Absent some other motivation for combining the reference teachings Applicants' respectfully submit that, on this basis alone, the Examiner has failed to establish a *prima facie* case of obviousness of claim 8. However, even if the reference teachings were properly

combinable in the manner suggested by the Examiner, there would still be no *prima facie* case of obviousness, because the claimed method would not be obtained.

Claim 8 recites "mounting an intervertebral disc endoprosthesis . . . so that outer surfaces of the . . . endoprosthesis mate with the previously milled bone surfaces and are capable of motion relative to each other." In other words, after the endoprosthesis is mounted, the outer surfaces are capable of movement relative to each other. By contrast, the axial movement of the prosthesis of Sheppard occurs only before the prosthesis is mounted in the intervertebral space. There is no motion of the outer surfaces of the Sheppard prosthesis relative to each other after expansion of the prosthesis is complete.

Applicants respectfully submit that, for each of the reasons set forth above, the Examiner has failed to establish a *prima facie* case of obviousness over Sheppard in view of Michelson, and that this rejection should be withdrawn.

V. OBVIOUSNESS REJECTION OVER MONSON

At pages 3-4 of the Office action, the Examiner has rejected claims 9, 20 and 21 as obvious under 35 U.S.C. § 103(a) over Monson. Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

The deficiencies of Monson have been described in some detail above with respect to the anticipation rejection of claims 4, 10, 11, 15, 16 and 19, and that description is incorporated by reference here.

Neither Monson, nor any of the cited art of reference, teach or suggest "forming dome-shaped, concave surfaces in adjacent spinal vertebral bodies," as required in claim 9. As described above, Monson teaches merely removal of damaged disc material and subsequent retraction of the vertebral bodies (without modifying their surfaces) so that a rolled-up, deflated prosthesis can be inserted, unrolled and inflated to conform to the natural surfaces of the endplates. As a result, the Examiner has failed to establish a *prima facie* case of obviousness, and this rejection should be withdrawn.

Applicants submit that this application is in condition for immediate allowance. The Examiner is invited to contact the undersigned at the numbers provided below if further

consideration is required. Also, Deposit Account No. 08-1394 may be used for any over or under payments.

Respectfully submitted,



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December 26, 2002

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**Claim Amendments As Compared to
The Previously-Filed Amendment**

4. (Amended Thrice) A method of surgery comprising :
- [(a)] forming concave, non cylindrical surfaces in the endplates of confronting vertebral bodies, and
- [(b)] inserting between the formed concave surfaces an intervertebral disc endoprosthesis including:
- [(1)] confronting [concaval-convex] supports, each support having an exterior convex surface adapted to mate with one of the formed concave surfaces, and
- [(2)] a resilient body interposed between the [concaval-convex] supports.

9. (Amended Thrice) A method of endoprosthetic discectomy surgery comprising:

receiving information about the size, shape, and nature of a patient's involved natural spinal vertebral bodies and natural spinal vertebral discs from imaging devices,

removing at least the involved, damaged natural spinal disc material from the patient's spine,

forming dome-shaped, concave surfaces in adjacent spinal vertebral bodies, and

implanting into the patient's spine, an intervertebral disc endoprosthesis comprising a resilient disc body and concaval-convex elements that at least partly surround and are capable of movement relative to the resilient disc body in the patient's spine.

(12) (Amended) [The method of surgery according to claim 4, further] A method of surgery comprising:

forming concave surfaces in endplates of confronting vertebral bodies,

inserting between the formed concave surfaces an intervertebral disc endoprosthesis,

comprising:

confronting concaval-convex supports, each support having an exterior convex surface adapted to mate with one of the formed concave surfaces, and

a resilient body interposed between the concaval-convex supports such that the supports are capable of movement relative to the resilient body element after the

endoprosthesis has been inserted between the formed concave surfaces;

[(c)] prior to forming the concave surfaces in the vertebral body endplates, [threadably] implanting [an] at least one anchor into a [precisely positioned] hole having a predetermined position in [the] an anterior surface of [each] at least one adjacent vertebral body; and

[(d)] affixing a bone surface milling [jig] mechanism to the [anchors] at least one anchor.

17. (Amended) [The method of surgery according to claim 16] A method of surgery comprising:

forming concave surfaces in the endplates of confronting vertebral bodies, and
inserting between the formed concave surfaces an intervertebral disc endoprosthesis,
including:

confronting concaval-convex supports, each support having an exterior convex surface adapted to mate with one of the formed concave surfaces,
a resilient body interposed between the concaval-convex supports, and
a fluid-tight seal member surrounding the resilient body, wherein the seal member comprises a flexible polymer [sheet] substantially impervious to the passage of any fluid.

18. (Amended) [The method of surgery according to claim 16] A method of surgery comprising:

forming concave surfaces in the endplates of confronting vertebral bodies, and
inserting between the formed concave surfaces an intervertebral disc endoprosthesis,
including:

confronting concaval-convex supports, each support having an exterior convex surface adapted to mate with one of the formed concave surfaces,
a resilient body interposed between the concaval-convex supports, and
a fluid-tight seal member surrounding the resilient body, wherein the seal member is affixed to the concaval-convex supports by a groove encircling the periphery of each support and a retaining band to retain the edge of the seal member in the groove.